

OCT 19 1999



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

M.C. Meinert, Esq.
Genetics Institute, Inc.
Legal Affairs
87 Cambridge Park Drive
Cambridge, MA 02140

Re: Patent Term Extension
Application for
U.S. Patent No. 5,171,569

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,171,569, which claims the human biological product BeneFIX™ (coagulation factor IX (Recombinant)), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 423 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of 423 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of August 4, 1998 (63 Fed. Reg. 41,579). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (583) + 166 \\ &= 458 \text{ days}\end{aligned}$$

Since the regulatory review period began January 26, 1995, after the patent issue date (February 11, 1997), the entire period has been considered in the above determination. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 458 days, would extend the patent from December 15, 2009 to March 18, 2011, which is beyond the 14-year limit (the approval date is February 11, 1997, thus the 14 year limit is February 11, 2011). The period of extension is thus limited to , by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, February 11, 1997, to and including February 11, 2011, or 423 days.

The limitations of 35 U.S.C. § 156 (g)(6) do not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

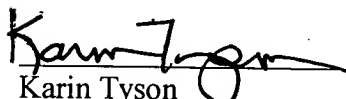
U.S. Patent No.:	5,171,569
Granted:	December 15, 1992
Original Expiration Date ¹ :	December 15, 2009
Inventors:	Donald S. Anson, et al.
Owner of Record:	British Technology Group Limited
Title:	Factor IX Preparations Uncontaminated By Plasma Components of Pox Virus
Product Trade Name:	BeneFIX™ (coagulation factor IX (Recombinant))
Term Extended:	423 days
Expiration Date of Extension:	February 11, 2011

Any correspondence with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

By FAX: (703) 308-6916
Attn: Karin Tyson

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.


Karin Tyson
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: David T. Read
Acting Director Regulatory Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike HFD-7
Rockville, MD 20852

RE: BeneFIX™
FDA Docket No.: 97E-0168

¹Subject to the provisions of 35 U.S.C. § 41(b).